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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,720	09/29/2006	Isamu Koyama	740819-1160	9395
78198	7590	07/21/2010		
Studebaker & Brackett PC One Fountain Square 11911 Freedom Drive, Suite 750 Reston, VA 20190			EXAMINER SZPRA, JULIE ANN	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			07/21/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/594,720

**Applicant(s)**

KOYAMA ET AL.

**Examiner**

JULIE A. SZPIRA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's arguments, see Appeal Brief, filed 4/8/2010, with respect to the rejection(s) of claim(s) 1, 2, 4-7 and 10 under U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites the limitation "reinforcement element" in line 15. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, the examiner is taking the "reinforcement element" to actually be the "reinforcement member" as claimed earlier in the claim. However, appropriate correction is required in a subsequent response.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1, 2, 4-7 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols (**US 3,088,466**) in view of Jones (**US 4,278,081**).

**Regarding claims 1, 2 and 4-7**, Nichols discloses a supporting device capable of supporting insertion of a medical instrument into a human body, comprising: a tubular member (1) includes a tubular member engagement section (15), the tubular member further includes an inner passageway between its opposite ends through which the medical instrument is capable of passing, wherein the tubular member is configured to guide the medical instrument into a digestive organ from an oral cavity through a pharynx, the tubular member is formed in a curved shape (Figure 1) in advance to conform to the shape of pharynx, and the tubular member has a diameter that is larger than that of the pharynx to allow an expansion of the pharynx; a guiding member (3) configured to guide the tubular member and the reinforcement member, the guiding member includes a guiding member engagement section (13) and the guiding member has a diameter smaller than that of the inner passageway, and when inserted from an oral cavity into the pharynx and retained there, the tubular member can

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guide the medical instrument to the digestive organ through the inner passageway, and such that when the guiding member engagement section is engaged with the tubular member engagement section, the digestive organ end of the guiding member is generally coincident with the digestive organ end of the tubular member (column 4, line 71-column 5, line 5), but fails to disclose the tubular member having a slanted distal end and containing a reinforcement element.

However, Jones teaches a tubular member with a slanted distal end, (Figure 2) molded to contain a spiral reinforcement element (70) therein that extends within the inner passageway along a longitudinal centerline, but does not extend past the distal end of the tubular member (column 7, line 66-column 8, line 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tubular member having a slanted distal end and including a spiral reinforcement member to support the patency of the lumen of the tubular member, while still allowing a degree of flexibility, while reducing pressure at the distal end of the device (column 8, lines 3-7; the slanted end does not exert pressure 360° within the tubular organ at the distal end, thus relieving the pressure at that end).

The guiding member (3) can be placed within the body prior to that of the tubular member (1), in that the guiding member and the tubular member are engaged with a force-fit, and the guiding member has the ability to be placed within the body prior to that of the tubular member, and then tubular member

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force fit over the guiding member. Nichols does not specifically disclose the device being used this way, but it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

**Regarding claim 10**, Nichols discloses the tubular member and the guiding member made of a variety of materials (column 1, lines 34-50), but fails to specifically disclose the guiding member made of a resin material harder than that of the tubular member.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the guiding member of a resin material harder than that of the tubular member, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Response to Arguments***

8. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. S./  
Examiner, Art Unit 3731  
July 16, 2010

/Gary Jackson/  
Supervisory Patent Examiner  
TC 3700  
July 18, 2010